IFW Atty. Dkt. No. 036481-0146



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Scott UMLAUF

Title:

NUCLEIC ACID VACCINE COMPOSITIONS HAVING A

MAMMALIAN CD80/CD86 GENE PROMOTER DRIVING

ANTIGEN EXPRESSION

Appl. No.:

10/748,124

Filing Date: December 31, 2003

Examiner:

Unassigned

Art Unit:

Unassigned

## INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The U.S.P.T.O. has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

Applicant submits herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S.P.T.O. in parent application Serial No. 09/705,022, filed November 1, 2000. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since Information Disclosure Statement U.S., Appln. No.: 10/748,124

they were previously submitted to the United States Patent & Trademark Office in the aboveidentified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

## RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language documents is explained in the parent application.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

Information Disclosure Statement U.S., Appln. No.: 10/748,124

even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

FOLEY & LARDNER LLP Customer Number: 27476 Telephone: (202) 672-5483

Facsimile:

(202) 672-5399

Richard C. Peet

Attorney for Applicant Registration No. 35,792

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitute for form 1449B/PTO		Complete if Known	
	Application Number	10/748,124	
TOUST ATTEMENT BY APPLICANT	Filing Date	12/31/2003	
	First Named Inventor	Scott UMLAUF	
Date Submitted: July 30, 2004	Group Art Unit	Unassigned	
(use as many sheets as necessary)	Examiner Name	Unassigned	
Sheetypage 1 of 3	Attorney Docket Number	036481-0146	

Examiner Initials*		U.S. Patent D	ocument	Name of Patentee or Applicant of Cited Document	Date of Publication of	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	Cite No. <sup>1</sup>	Number	Kind Code <sup>2</sup> (if known)		Cited Document MM-DD-YYYY	
	A1	US 4,945,050		SANFORD et al.	07-31-1990	
	A2	US 5,100,792	Α	SANFORD et al.	03-31-1992	
	A3	US 5,120,657	Α	McCABE et al.	06-09-1992	
	A4	US 5,149,655	Α	McCABE et al.	09-22-1992	
	A5	US 5,187,077	Α	GEARING et al.	02-16-1993	
	A6	US 5,204,253	Α	SANFORD et al.	04-20-1993	
	A7	US 5,584,807	Α	McCABE	12-17-1996	
	A8	US 5,589,466	Α	FELGNER et al.	12-31-1996	
	A9	US 5,630,796	Α	BELLHOUSE et al.	05-20-1997	
	A10	US 5,738,852	Α	ROBINSON et al.	04-14-1998	
	A11	US 5,865,796	Α	McCABE	02-02-1999	
	A12	US 6,168,587	B1	BELLHOUSE et al.	01-02-2001	
	A13	US 6,194,389	B1	JOHNSTON et al.	02-27-2001	
	A14	US 6,339,068	B1	KREIG et al.	01-15-2002	

								-
				FC	DREIGN PATENT DOCUMEN	TS		
Examin er Initials*	Cite No.1	Fo Office <sup>3</sup>	oreign Patent D Number <sup>4</sup>	ocument Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	A15	wo	94/24263	A1	OXFORD BIOSCIENCES LIMITED	10-27-94		
	A16	wo	96/04947	A1	OXFORD BIOSCIENCES LIMITED	02-22-1996		
- Marin III III III III III III III III III I	A17	wo	96/12513	A1	OXFORD BIOSCIENCES LIMITED	05-02-1996		
	A18	wo	96/14855	A1	AGRACETUS, INC.	05-23-1996		
	A19	wo	96/20022	A1	OXFORD BIOSCIENCES LIMITED	07-04-1996		
	A20	wo	97/32987	A1	UNIVERSITY OF TORONTO	09-12-1997		
	A21	wo	97/48485	A1	POWDERJECT RESEARCH LIMITED	12-24-1997		
	A22	wo	98/10750	A2	POWDERJECT RESEARCH LIMITED	03-19-1998		
	A23	wo	98/28332	A2	BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM	07-02-1998		

Examiner	Date	
Signature	Considered	
U.ga.a.a		·

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitute for form 1449B/PTO	Complete if Known		
INFORMATION DISCLOSURE	Application Number	10/748,124	
STATEMENT BY APPLICANT	Filing Date	12/31/2003	
JUL 3 0 2000 ate Submitted: July 30, 2004	First Named Inventor	Scott UMLAUF	
III 3 Date Submitted: July 30, 2004	Group Art Unit	Unassigned	
(use as many sheets as necessary)	Examiner Name	Unassigned	
Speet 2 of 3	Attorney Docket Number	036481-0146	

	-	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A24	ARMITAGE et al., <i>Nature</i> (1992), 357:80-82.	
	A25	BRANKENHOFF et al., <i>Immunol.</i> (1987), 139:4116-4121.	1
	A26	CHEN et al., Journal of the American Society of Hematology (1995), 86(10):Abstract No. 963.	
<del></del>	A27	ELLIS et al., <i>J. Immunol.</i> (1996), 56:2700-2709.	
	A28	FONG et al., <i>J. Immunol.</i> (1996), 157:4442-4450.	
	A29	FREEMAN et al., <i>Immunology</i> , 2 <sup>nd</sup> Ed. (1994), pp. 19-20, 89-90, 103-106 and 297-298.	<del>                                     </del>
	A30	FREEMAN et al., <i>Science</i> (1993), 262:909-911.	
*****	A31	GURUNATHAN et al., <i>J. Immunol.</i> (1998), 161:4563-4571.	
	A32	JENKINS, M.K., Immunol. Today (1992), 13:69-73.	1
	A33	JOSIEN et al., J. Immun. (1999), 162:2562-2568.	
	A34	LAI et al., DNA and Cell Biol. (1995), 14:643-641.	
	A35	LI et al., "Cloning and Functional Characterization of the 5'-Regulatory Region of the Human CD86 Gene," Human Immunology (2000), 61:486-498.	
	A36	LIU, Y. et al., J. Exp. Med. (1992), 175:437-445.	
	A37	LYMAN, et al., <i>Oncogene</i> (1995), 11(6):1165-72.	
	A38	MACKEY et al., J. Immunology (1998), 161:2094-2098.	
	A39	MANIATIS, et al., Molecular Clonging: Laboratory Manual, Cold Spring Harbor: 406-407.	
	A40	MENDOZA et al., <i>J. Immunology</i> (1997), 159:5777-5781.	
	A41	MORGAN et al., Science (1976), 193:1007-1008.	
	A42	NABAVI et al., <i>Nature</i> (1992), 360:266-268.	1
	A43	NAUJOKAS, M.F., et al., Cell (1993), 74:257-268.	
	A44	NGO et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," In: <u>The Protein Folding Problem and Tertiary Structure Prediction</u> . (1994), Ch. 14: 491-494.	
	A45	PULENDRAN et al., <i>J. Exp. Med.</i> , 188:2075-2082, 1998	
	A46	ROMANI et al., J. Invest. Dermatol. (1989), 93:600-609.	1

Examiner Signature		Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents, <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	Substitute for form 1	449B/PTO	Complete if Known		
OIPA	FORMATION DIS	CLOSURE	Application Number	10/748,124	
s S	TAREMENT BY A	PPLICANT	Filing Date	12/31/2003	
/ .	اري) احداد (ادران المحداد (ادران المحدد)	20. 2004	First Named Inventor	Scott UMLAUF	
ho 1111 3 0 2√1	ate Submitted: Jul	y 30, 200 <del>4</del>	Group Art Unit	Unassigned	
A (use	as many sheets a	as necessary)	Examiner Name	Unassigned	
Sheet	3/	of 3	Attorney Docket Number	036481-0146	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A47	SCHULER et al., J. Exp. Med. (1985), 161:526-546.	
	A48	SCHWARTZ, R.H., Cell (1992), 71:1065-1068.	1
	A49	SCHWARTZ, R.H., <i>Science</i> (1990), 248:1349-1356.	
	A50	SELVAKUMAR et al., Immunogenetics (1993), 38:292-295.	<del> </del>
	A51	SPRIGGS et al., J. Exp. Med. (1992), 176:1543-1550.	<del> </del>
	A52	SPRIGGS, Immunol Ser. (1992), 56:3-34.	
	A53	TACKET et al., "Phase 1 Safety and Immune Response Studies of a DNA Vaccine Encoding Hepatitis B Surface Antigen Delivered by a Gene Delivery Device," Vaccine (1999), 17:2826-2829.	
	A54	VAN SEVENTER, G.A., <i>J. Immunol.</i> (1990), 144:4579-4586.,	
	A55	WONG et al., J. Biol Chem (1997), 272(40):25190-4.	
	A56	WONG et al., J. Exp. Med. (1997), 186:2075-2080.	
	A57	WONG et al., J. Immunol. (1999), 162:2251-2258.	
	A58	ZHANG et al., <i>Gene</i> (1996), 183:1-6.	

Examiner Signature	Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁵Applicant is to place a check mark here if English language Translation is attached.